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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,220	06/22/2000	Alfred H. Dougan	4045-0109P	7800

2292 7590 05/09/2003

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EXAMINER
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MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/09/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/599,220

Applicant(s)

DOUGAN ET AL.

Examiner

Sean R McGarry

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17, 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

Claims 16, and 18-27 remain rejected and newly added claims 29 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendment filed 9/18/02 introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "a protein having a half-life in serum of greater than 1.5 hours" in claim (and those claims that depend from claim 16). It is noted that page 7 of the specification appears to provide support for half-life spans but not that instantly amended into claim 16.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instantly claimed invention is broadly drawn to include any and all oligonucleotides that may bind to any and all proteins that may be a component of a mammalian clotting cascade and also includes any and all proteins that may be bound to the 3' and/or 5' end of the oligonucleotide to provide for an extended half life of an oligonucleotide aptamer in blood. Applicants arguments filed 3/3/03 are addressed in this new rejection under 112 first paragraph written description.

The instant specification discloses two aptamer oligonucleotides that were known in the art at the time of invention (see US 5,756,291, for example) that bind to thrombin where streptavidin or biotin was conjugated to the 3' and/or 5' ends. The disclosure of these two known sequences with biotin or streptavidin conjugated to the 3' and/or 5' end does not allow one in the art to immediately envision the structure of other oligonucleotide aptamers that bind to different proteins that may be a component of a mammalian blood clotting cascade which have been complexed with a protein at the 3' and/or 5' end that provided for an extended half life in blood. Applicant has offered several references that show aptamers to thrombin (paper Nos 16 and 17, filed 3/3/03). Aptamers to thrombin do not provide a correlation of structure and function for the scope claimed. The disclosure of oligonucleotide aptamer structures that bind to thrombin does not provide one in the art with a structure that correlates to binding of a blood clot (other than to thrombin) or to a protein that is a component of a mammalian blood-clotting cascade. Further, the disclosure of the ability of streptavidin to impart an


extended half-life does not provide a structure that correlates to the function of extending the half-life of an oligonucleotide aptamer in blood. Is it merely the addition of any protein to an oligonucleotide that provides this property or does the protein need to have some structure to provide this capacity [extension of half life in blood]. For example, would one expect to increase the half life of an oligonucleotide by 20 seconds with the conjugation of avidin since it was known in the art that avidin has a half life of 20 seconds in blood (see applicant arguments paper No.12, filed 9/18/02)? The specification, as filed, has not shown that the structure of aptamers to thrombin correlate to structures that will bind to different proteins and has not shown that the structure of streptavidin [or what particular structure(s) of streptavidin] correlate to the function of extending the half life of an oligonucleotide aptamer when conjugated to the 3' and/or 5' end(s) thereof. The instant disclosure of a few species is clearly not representative of the genus instantly embraced in the claims. The members of the genus are highly divergent since each aptamer oligonucleotide varies in sequence and such sequences are not predicable but must be found *de novo* for each and every target protein (see US 5,756,291, for example). Each aptamer has different properties and structure. The instant specification fails to provide sufficient species to describe the structures embraced in the claims by a disclosure of sufficiently detailed, relevant identifying characteristics and have not provided, for example, functional characteristics [extension of half life in blood or aptamers that bind to blood clots or proteins of a mammalian blood clot cascade] coupled with a known or disclosed correlation between function and structure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM  
May 7, 2003

  
SEAN McGARRY  
PRIMARY EXAMINER  
1635